June 23, 2020

Office of Inspector General  
Department of Health and Human Services  
Attention: OIG-2605-P  
Cohen Building  
330 Independence Avenue SW, Room 5527  
Washington, DC 20201

Submitted electronically at: http://www.regulations.gov

RE: Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General’s Civil Money Penalty Rules [OIG-2605-P]

Dear Office of Inspector General,

OCHIN is grateful for the opportunity to respond to this proposed rule regarding information blocking and civil money penalty rules. As the implementation dates of the Information Blocking and Interoperability Rules rapidly approach, we are pleased more work is being done to provide clarity and guidance for organizations impacted by this legislation.

OCHIN is a 501(c)(3) not-for-profit community-based health information technology (HIT) collaborative, and a national leader in promoting high-quality health care in historically underserved areas across the country. We are a system of over 500 health centers, including Federally Qualified Health Centers (FQHCs), Rural Health Centers (RHCs), correction facilities, Ryan White Centers, and public health agencies, connecting them together on a single instance of Epic customized for the ambulatory health providers. As we assist underrepresented organizations to whom these rules apply, we believe our perspective is critical to ensure these providers and the systems supporting them are not disproportionately impacted. Through our feedback, we hope to help OIG avoid unintended inequities as a consequence of this rule.

OCHIN has long been a strong proponent of interoperability to improve safety and coordination of patient care, and overcoming information blocking practices is a requisite part of data movement. We strongly support the goals of interoperability but have reservations regarding some of the potential impacts of these rules on providers, health organizations, and patients based on both timelines and outcomes.

COVID-19 has caused us to enter into an unprecedented and historic time in health care delivery. Health centers were required to drastically transform their care delivery methods with a focus on virtual care. The enormous resource push to innovate in this space has irreparably changed the feasible timeline for implementing new rules, especially those as impactful as the Interoperability and Information Blocking Rules. Those on the front lines responding to the influx of COVID-19 patients who are still rising in numbers are simultaneously being asked to implement enormous changes to ensure compliance, and few have the resources to respond this quickly to an unfunded mandate. Given the current and ongoing circumstances with COVID, we are giving the following feedback to improve implementation outcomes and provide necessary clarity for actors through this rule:
In light of current events, we strongly request a deadline extension, as health systems need more time to implement changes before enforcement penalties begin;

- Ensure consideration is provided when pursuing compliance issues out of an actor’s control (COVID-19 impacts, staffing and resource issues);
- Provide clear guidance for how the OIG will interpret ONC’s definitions to classify organizations which fall into multiple actor categories at the time a violation is pursued;
- Administer greater clarity regarding how penalties will be effectively applied, preferably with hypothetical examples and how the agency will determine “intent”; and
- Protect provider organizations and patients from increased liability and risk of forcing data movement from a HIPAA-regulated environment to an unregulated environment.

Unintended Inequities

Not all health organizations come equipped with the same resources when it comes to compliance or upgrades to meet new requirements. This reality existed prior to the current pandemic but has taken a new shape, given the enormous economic disruption since COVID-19 swept the nation—particularly within health care. All providers felt the consequences, but the more devastating impact was on the safety net and smaller rural health centers. Furthermore, the full impacts are not yet known, as current case numbers continue to fluctuate, and there are predictions of additional waves that may reanimate quarantines. For these reasons, we ask for an extension of the finalized date of enforcement to December 31, 2021.

This administration sought to improve regulations to reduce the burden on providers and improve the movement of data. However, this rule has the opposite impact, requiring an increase in legal and compliance staff and resources to ensure an organization can reduce its liability while simultaneously protecting its providers and their patients. Where legal and compliance teams are not equal between health care organizations, requiring all organizations to enact their internal policies of how to comply with these rules puts a substantial burden on the safety net and small rural providers.

As OCHIN works with organizations of various sizes, our concern is the devastating impacts this may have on smaller organizations with tighter budgets. In the wake of COVID-19, many of these health centers in underserved parts of the nation have faced extreme hardships. For example, rural health centers with patient populations unserved by broadband could not utilize virtual care to the level needed, causing them to have to shut their doors for lack of billable visits. Will this RHC be considered data blocking when it cannot remain open to respond to requests, or even when they come back on but cannot afford to reconnect their internet for a matter of months? An enforcement action during this time, or even shortly thereafter, could bankrupt this organization, leaving their patients in dire straits. These are the injustices we seek to avoid in the premature enforcement of this rule.

The requirement for all health organizations to sign onto agreements for unfettered data transfer overlooks those supporting safety net and small rural providers without such resources or the ability to affordably outsource these needs. Regardless of whether deadlines are extended, we respectfully request that OIG give substantial weight to compliance issues out of an actor’s control (COVID-19 impacts, staffing and resource issues) to reduce or avoid CMPs, and have a mechanism in place to help the organization get access to the assistance it requires for future compliance.
Application of CMPs

The Cures Act authorizes civil monetary penalties (CMPs) for a developer of certified health information technology (HIT), an entity offering certified HIT, a health information exchange (HIE), or a health information network (HIN). Not only are these distinctions not defined with any definitive clarity, but there are also organizations that fit into multiple distinctions at any given time, complicating expectations and, therefore internal operations for compliance purposes. We urge for greater clarity as to how these different activities will be interpreted regarding CMPs prior to any active enforcement date.

When CMPs are being considered for a violation of the Cures Act, will the organization’s role be determined based upon a totality of their activities or the activity they were participating in at the time of violation? For example, if the organization is solely acting on its certified HIT license to deploy an instance of an electronic health record (EHR) to a provider (therefore, an entity offering certified HIT), but they are primarily considered a HIN although not acting as such at the time, how would the penalties apply? We cannot imagine the circumstances where the organization, falling into both categories at a single time, would be hit with duplicative penalties as “two actors” at the time of the violation. These questions require clarity on the assumption the penalties would be applied in a more reasonable fashion, preferably with the lower applicable CMP amount.

Also of concern--the potential penalties imposed by this rule, where some critical elements remain unclear, could be interpreted to have dangerous policy impacts. We need to better understand how violations are counted and what the resulting penalty amounts are. For example, are penalties imposed per organization impacted by the temporary information blocking, or is it interpreted per patient impacted? What is the threshold to determine “knowingly,” which defines a violation, and what proof is required to meet this threshold? How these questions are answered means the survival or demise of the few organizations supporting Federally Qualified Health Centers (FQHCs), Rural Health Clinics (RHCs), and others within the safety net.

As an organization supporting providers caring for Medicaid or uninsured patients, concerns have arisen regarding what, if any, leniency will be afforded for unintentional or accidental violations deemed as “known” violations or if the provider or organization’s financial capability will be considered in the analysis of determining penalties. We request greater clarity of how the agency will interpret and determine “intent,” with a particular focus on the entities mentioned above. With the continual rise of mergers and acquisitions resulting in health care monopolies in many areas around the nation, a rule that increases this occurrence by bankrupting those who support safety net providers will only harm patient health further—the antitheses of what these rules aim to do.

Unresolved Risks and Liabilities

Although OCHIN has expressed this concern in the two prior comments to ONC and CMS, we feel the need to reiterate that this remains unaddressed. The mandate for movement of patient information from a HIPAA-covered environment to a non-HIPAA covered and otherwise minimally regulated environment creates a high risk for the patient and liability for the provider. The result is an inequitable structure, one covered by the law, and one with minimal oversight, creating inevitable inequity between those who generate the record and those receiving a continuous flow of highly valuable data.

Last year, HHS provided guidance that releases liability from the covered entity once the health information is transferred upon the consent of the patient. However, lawsuits initiated by a patient whose information has been released citing the provider as a responsible party can still be expected. For many
safety net providers, the legal costs associated with these types of actions would become quickly unmanageable, putting their slim resources at risk. To prevent this, statutory protections are needed for providers releasing a patient’s PHI into the unregulated environment at the request of the patient.

We again urge that specific protections be put in place that covers any environment where personal health information (PHI) may enter. The high incidence of health data sharing by unregulated apps and the lack of transparency puts patients at even greater risk when personal health information can move with no restrictions or protections.\(^1\)\(^2\) Further, there is great concern that a misunderstood consent may be given to reuse PHI for profit unbeknownst to the patient, leaving them a substantial loophole to avoid any potential legal action. As 91% of the population does not take the time to read terms of service, this concern is not unfounded,\(^3\) and this does not even take language barriers into consideration.

We appreciate your consideration of our comments. Please contact Jennifer Stoll at stollj@ochin.org should you have any questions.

Sincerely,

Jennifer Stoll
EVP, Government Relations and Public Affairs
OCHIN

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